

In the Application of:
Jesse H. GAYTAN
Serial No. 09/801,871

REMARKS

Applicants acknowledge that claims directed to the process of manufacture now stand as nonelected pursuant to the Restriction Requirement in Paper No. 6. Applicant continues to traverse the basis for the restriction requirement and have presented conforming amendments herein in the event that the examiner reconsiders the Requirement and rejoin the nonelected claims.

Claims 46 and 48 have been amended to address the claim issues noted by the examiner.

Claims 32, 34, 36-40 and 42-44 now stand rejected as anticipated by Kishino et al. US 4,150,155. From the examiners candid comments, he notes that no weight will be given to process steps associated with the manufacture of the claimed composition or to a product-by-process format employed in claim 42. The same rationale is applied to claim 43 and its requirement for an "extrudable . . . solid composition" that comprises the listed ingredients. As will be apparent in a moment, applicant must respectfully traverse the basis for the rejection and the proposed claim construction presented by the examiner.

Moreover, it is improper to ignore claim limitations or evaluate dissected elements in isolation. See, MPEP § 2106. Functional language is expressly permitted by MPEP § 2173.05(g) as well as product-by-process claims in MPEP § 2173.05(p).

As discussed and explained in the specification, the invention relates to an extruded composition that contains a phosphoroamido(di)thioate active ingredient. Acephate is a preferred compound as the active ingredient and is most conveniently described in that context.

Acephate is characterized by a sensitivity to elevated temperatures such as that experienced during conventional milling and extrusion granulation processes. When exposed to excess heat, the crystalline structure of the acephate changes from an active form to an inactive form. Additionally, excess heat during the processing operations can cause a fire in the milling plant or result in undesired activity degradation of a final granule. Thus, acephate milling operations are often limited to refrigerated facilities or seasons where the ambient temperature is sufficiently cold to offset the frictional heat of the milling

operation and keep the acephate below its critical temperature. Note the "Background" of the invention in the specification and see generally the "Background" section of Jadhav et al. WO 03/051606. Thus, the heat history of the manufacturing process is reflected in the final composition by way of the activity level (% active crystalline structures) of the active ingredient so that a final composition that has not been exposed to high processing heats should be generally more active than corresponding compositions that have been exposed to high heats, however briefly.

This heat sensitivity is also a primary reason why there are few commercially available granulated forms of acephate – the frictional heat caused by passage under pressure thru the extrusion die is so high that the acephate becomes deactivated and a fire hazard. Elaborate die cooling equipment, controlled water addition for internal cooling, and a variety of processing additives have been used in the prior art in attempts to ameliorate the frictional heat of extrusion. These additional ingredients reduce the amount of active ingredient that can be put into the granule and often degrade the structural integrity of the final granule. Addition of cooling water to the extrusion mass affects the integrity of the fresh extrudate and requires additional drying time to get the residual moisture content to 1 wt% or less.

An additional complication in the manufacture of granulated acephate is a sensitive of the active ingredient to residual amounts of moisture in the granule upon storage. It has been determined that residual moisture levels of more than 1 wt% will cause hydrolysis of the acephate with an attendant drop in the effectiveness of the granulated composition. Thus, granulated acephate needs to be well dried and stored so as to prevent absorption of ambient moisture *or* the manufacturing history of the composition needs to be free of exposure to water.

The present invention addresses both of these problems. The use of a lubricious polymer resin component (preferably a poly(alkylene oxide) resin) along with a small, effective amount of a solvent for that polymer provides an extrusion mass that is very slippery. This lubricity allows the active ingredient solids to slip past one another and over the sharp edges of the extrusion die even while under high compaction pressures. The net

result of a low friction extrusion process is a compacted extrudate composition that is not exposed to high frictional heats thru the extrusion die.

At less than 3 total wt% solvent (based on the total weight of the extrudable mixture with the active ingredient), there is enough solvent to form a highly concentrated liquid when mixed with only the polymeric lubricant. This slippery liquid is preferably sprayed onto the dry active ingredient solids. It might be said that the extrudate mass is a "barely damp" or "barely wetted" mixture of solid particles that will compact and dry to a solid composition of high structural integrity. The lubricating polymer resin, when dried, acts as a binder for the composition that provides the structural integrity and durability. The prior art has not used or disclosed such a composition or its intertwined manufacturing process.

The present lubricating polymer also permits (but does not require) the use of a small amount of nonaqueous solvent to provide the surface lubricity for the extrusion mass. Solvent removal and recovery is desirable but allows the composition to avoid the introduction of water that might cause hydrolysis upon exposure.

The claimed invention follows the above explanation of the invention. Claim 32 (as amended) requires 0.2-3 wt% of a "poly(alkylene oxide) polymeric lubricant" and a residual amount of less than 1 wt% of a solvent for that polymeric lubricant. Claim 36 lists a variety of solvents that can be used, including water, while claims 37-40 are water-free (the azeotrope of claim 40 not being the same as free water). Claim 41 provides for the inclusion of a small amount of a silica anticaking agent. New claim 52 requires that the composition be exposed to a heat history that includes no more than a 4° C temperature rise thru the extruder (with the attendant preservation of the active crystalline structure associated with the active ingredient).

Kishino et al. teaches the preparation of a liquid pesticide (note examples 1 and 2) which can be formulated with one or more emulsifying agents (see, col. 9) to make a liquid emulsion. As described in col. 8, one or more carrier vehicles (liquids, solids, etc.) can be used to provide a dispersal mechanism. The active ingredient is not, however, a solid particle, does not include solid particles of active ingredient bound together with a polymeric binder that also acts as a lubricant in an extrusion manufacturing process.

Notably, there is no teaching that one should, or could, use a poly(alkylene oxide) polymeric lubricant and binder to extrude a structurally sound granule with low friction through the die and the attendant preservation of activity of a heat-sensitive phosphoroamido(di)thioate.

Having failed to teach each element of the claimed invention, the rejections for anticipation should be withdrawn.

Because there is also no teaching or suggestion to make the claimed invention, the rejections for obviousness that are based on Kishino et al. should also be withdrawn. Kishino et al. fails to teach that one could or should (a) make a granule of active solid ingredients (b) that are bound by a polymeric binder (c) that also acts as a highly effective lubricant during the extrusion manufacturing process.

The rejections for obviousness of record that are based on Chan et al. 5,100,667 should similarly be withdrawn.

Chan et al. teaches an acephate granule made by blending acephate solids with a nonionic polymeric surfactant that softens at a temperature within the range of 80° to 130° F (27° to 54° C). Exemplary surfactants are alkyl or aryl alcohol ethoxylates, and block copolymers of propylene and ethylene oxides of ethylene diamine (materials that are different than the claimed poly(alkylene oxide) lubricant/binder). See, col. 4. Importantly, the patent warns "no solvent is added to this composition" at col. 5, lines 2-3. Instead of lubricity (as in the present invention), the process disclosed in Chan et al. uses heat from friction in the extrusion process to soften the surfactant so as to act as a binder, like a hot melt glue. This hot melt binding mechanism is limited, however, to a functional minimum amount of binder that is higher than the polymeric binder used in present invention. Chan's hot melt binder system also requires an exceedingly finely milled surfactant that is well dispersed among the active ingredient solids thereby representing twin concerns for dust handling and the possibility of excess heat caused by thorough mixing techniques.

In contrast, the present invention provides a dissolved polymeric binder that can flow between particle interstices while in liquid form and harden when the solvent is removed.

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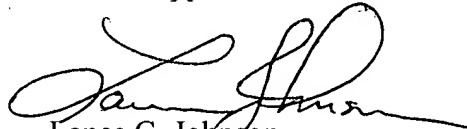
Chan et al. does not teach or suggest the present invention:

- Nothing teaches or suggests the general use of a solvent-dissolved polymeric lubricant and binder for the extrusion process. The only teaching discourages the addition of solvent into the composition (note the references to a dry mixture in col. 4, lines 60-63) and does not form a lubricious mixture to reduce friction thru the extrusion die. Indeed, frictional heat is desired in Chan et al. in order to increase the temperature of the extrusion mass so as to soften and/or melt the surfactant and bind together the composition. The present invention reduces frictional heat thru the extruder and the attendant loss in active ingredient that flows therefrom.
- There is no teaching or suggestion in Chan et al. that a poly(alkylene oxide) binder could also act beneficially as a lubricant for the extrusion mixture.
- There is no teaching or suggestion that only 0.2-3 total wt% of a poly(alkylene oxide) binder could provide adequate structural integrity to the final granule. All of the examples in Chan et al. use 5.2-6.2 wt% of the softenable surfactant.

Similarly, there is no combination of Kishino et al. and Chan et al. that could be made so as to form a *prima facie* case for obviousness of the claimed invention. There is no teaching in either reference that suggests the use of a poly(alkylene oxide) binder with enough solvent to form a lubricated, extrudable mass of phosphoroamido(di)thioate solids.

Reconsideration and allowance are respectfully requested.

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Date: October 25, 2004 (Monday)